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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/714,967	11/18/2003	Wayne Emmons	033836-001	4603
21839	7590	02/02/2006	EXAMINER	
BUCHANAN INGERSOLL PC (INCLUDING BURNS, DOANE, SWECKER & MATHIS) POST OFFICE BOX 1404 ALEXANDRIA, VA 22313-1404			DRODGE, JOSEPH W	
			ART UNIT	PAPER NUMBER
			1723	

DATE MAILED: 02/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/714,967	Applicant(s) EMMONS ET AL.	
	Examiner Joseph W. Drodge	Art Unit 1723	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cuomo et al patent 6,361,803 in view of Crea et al patent 6,165,475, and Husken et al patent publication US2002/0172751 and in view of the Tovar et al published article

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entitled "Changes in the Phenolic Composition of Virgin Olive Oil from Young Trees (*Olea europea* L. cv. Arbequina) grown under Linear Irrigation Strategies".

Cuomo et al disclose isolating of antioxidants, including oleuropein (column 7, lines 22-24), by methods employing obtaining water mixtures of raw olives and olive oil obtained therefrom (column 5, line 62-column 6, line 27), adding an acid (column 8, lines 29-45), and heat (column 6, lines 51-60), to the water, collecting anti-oxidant rich phase or constituents from the mixtures, followed by extracting the anti-oxidants and oleuropein with a solvent or mixture of solvents thereof that may comprise "acetone" {acetone being classifiable as a non-polar solvent even though Cuomo discloses acetone as being amongst a polar group of solvents}, (see column 8, lines 10-20), and finally removing the solvent or separating the solvent containing phase(s) from a residual oil or residual water phase (column 8, lines 21-28, et. Seq.) .

The claims firstly differ in requiring the water to comprise vegetation water. However, Crea et al teach to extract phenolic, antioxidant compounds from sources including such vegetation water (column 1, line 65-column 2, line 7 and column 2, line 57-column 3, line 20). It would have been obvious to have applied the Cuomo process to vegetation water, as taught by Crea et al, since vegetation water is abundant in water-soluble phenolic antioxidant compounds.

The claims also differ in requiring that specifically "oleuropein aglycon" be the antioxidant which is extracted, Cuomo naming only oleuropein. But Tovar et al teach that oleuropein aglycon is abundantly present in olive oil from olive plants, depending upon growing conditions and optimal irrigation practices (page 5502, etc.), and can be

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isolated and extracted by method steps including use of the non-polar organic solvent hexane (beginning at page 5503 in the paragraph entitled "Olive Oil Analysis"). It would have also been obvious to have applied the Cuomo process to extracting specifically oleuropein aglycon with use of non-polar solvents, as taught by Tovar, since such antioxidant possesses favorable flavor and color characteristics {Tovar at }, thus encouraging olive oil consumption.

The claims finally differ in requiring that the particular acid added comprises citric acid. However, Husken et al teach to increase the antioxidant, polyphenol content in olive oil by extracting oil from olive material in the presence of citric acid (see especially paragraph 10 of Husken). It would have also been obvious for the ordinarily skilled artisan to have chosen citric acid as the acid employed in the Cuomo process, since citric acid is a "food grade acid" and helps to obtain a clear oil having good taste and color properties and increased polyphenol level (Husken at paragraph 9).

Regarding claim 5, addition of citric acid in the claimed concentration is found at Husken paragraph 10, last sentence.

Claims 2-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cuomo et al in view of Crea et al, Tovar et al and Husken et al as applied to claim 1 above, and further in view of Luddy et al patent 4,880,658.

Claims 2-4 further differ in requiring the solvent to comprise a mixture of hexane and acetone, claims 3 and 4 requiring approximately equal amounts of the two solvents. However, Cuomo discloses that mixtures of solvents may be utilized (column 8, lines 15-18); while Tovar et al employs hexane solvent (page 5503). Attention is drawn to

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Luddy et al which state that mixtures of fats and oils from sources such as olive oil are effectively fractionated by dissolving in solvent mixtures, with acetone/hexane mixtures being among specifically taught solvent mixtures (see claim 4 of Luddy). It would have also been obvious to have employed an acetone/hexane mixture in the step of extracting oleuropein aglycon of the Cuomo process, since Tovar teach that hexane is effective in dissolving olive oil constituent rich in antioxidants including oleuropein aglycon, and since Luddy teaches that mixtures of solvents form azeotropes which facilitate formation of distinct phases which are readily separable by decantation and filtration.

Claims 6-10,12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cuomo et al in view of Crea et al, Tovar et al and Husken et al and also Guzman et al patent 6,849,770.

Cuomo et al disclose isolating of antioxidants, including oleuropein (column 7, lines 22-24), by methods employing obtaining water mixtures of raw olives and olive oil obtained therefrom (column 5, line 62-column 6, line 27), adding an acid (column 8, lines 29-45), and heat (column 6, lines 51-60), to the water, collecting anti-oxidant rich phase or constituents from the mixtures, followed by extracting the anti-oxidants and oleuropein with a solvent or mixture of solvents thereof that may comprise "acetone" {acetone being classifiable as a non-polar solvent even though Cuomo discloses acetone as being amongst a polar group of solvents}, (see column 8, lines 10-20), and finally removing the solvent or separating the solvent containing phase(s) from a residual oil or residual water phase (column 8,lines 21-28, et. Seq.) .

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The claims firstly differ in requiring the water to comprise vegetation water. However, Crea et al teach to extract phenolic, antioxidant compounds from sources including such vegetation water (column 1, line 65-column 2, line 7 and column 2, line 57-column 3, line 20). It would have been obvious to have applied the Cuomo process to vegetation water, as taught by Crea et al, since vegetation water is abundant in water-soluble phenolic antioxidant compounds.

The claims also differ in requiring that specifically "oleuropein aglycon" be the antioxidant which is extracted, Cuomo naming only oleuropein. But Tovar et al teach that oleuropein aglycon is abundantly present in olive oil from olive plants, depending upon growing conditions and optimal irrigation practices (page 5502, etc.), and can be isolated and extracted by method steps including use of the non-polar organic solvent hexane (beginning at page 5503 in the paragraph entitled "Olive Oil Analysis"). It would have also been obvious to have applied the Cuomo process to extracting specifically oleuropein aglycon with use of non-polar solvents, as taught by Tovar, since such antioxidant possesses favorable flavor and color characteristics {Tovar et al}, thus encouraging olive oil consumption.

The claims finally differ in requiring that the particular acid added comprises citric acid. However, Husken et al teach to increase the antioxidant, polyphenol content in olive oil by extracting oil from olive material in the presence of citric acid (see especially paragraph 10 of Husken). It would have also been obvious for the ordinarily skilled artisan to have chosen citric acid as the acid employed in the Cuomo process, since

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citric acid is a "food grade acid" and helps to obtain a clear oil having good taste and color properties and increased polyphenol level (Husken at paragraph 9).

Claim 6 and claims dependent therefrom add to claim 1, the additional process step of adding olive pomace oil. However, Cuomo also discloses adding mixtures of olive oil and olive oil sources before processing to obtain antioxidant-rich products at column line . Guzman teaches at column line that pomace oil, associated with olive oil wash water is rich in additional extractable anti-oxidants including hydroxytyrosol (Abstract, column 1, lines 25-31 and column 1, line 66-column 2, line 14). It would have also been obvious to one of ordinary skill in the art to have added pomace oil to the olive oil mixture disclosed by Cuomo et al, to also obtain antioxidant having anti-inflammatory, anti-aging and other useful antioxidant properties.

For claim 7, see Husken at paragraph 10 for amount of citric acid to employ.

For claim 8, Guzman suggests 5% , or about 10%, of olive oil in the form of pulp, i.e. pomace, obtainable from olive oil stock (column 1, lines 39-48).

For claim 9, Cuomo discloses heating to about 100 degrees C for one hour in Example 11, column 13, lines 64-65.

For claim 10, drying is disclosed by Cuomo at column 9, lines 44-45 to separate the antioxidant composition.

For claim 12, Cuomo discloses solvent removal step at column 8, lines 51-52.

For claim 13, treating the water used by means such as distilling is suggested by Cuomo at column 7, lines 32-33, suggested especially for recycling of the water.

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Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cuomo et al in view of Crea et al, Tovar et al, Husken et al and Guzman et al as applied to claim 6 above, and further in view of Luddy et al.

Claim 11 further differs in requiring the solvent to comprise a mixture of hexane and acetone, or approximately equal amounts of the two solvents. However, Cuomo discloses that mixtures of solvents may be utilized and that mixtures employing acetone are among the preferred solvent mixtures; while Tovar et al employs hexane solvent. Attention is drawn to Luddy et al which state that mixtures of fats and oils from sources such as olive oil are effectively fractionated by dissolving in solvent mixtures, with acetone/hexane mixtures being among specifically taught solvent mixtures (see claim 4 of Luddy). It would have also been obvious to have employed an acetone/hexane mixture in the step of extracting oleuropein aglycon of the Cuomo process, since Tovar teach that hexane is effective in dissolving olive oil constituent rich in antioxidants including oleuropein aglycon, and since Luddy teaches that mixtures of solvents form azeotropes which facilitate formation of distinct phases which are readily separable by decantation and filtration.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Caruso et al published Article entitled: "Rapid Evaluation of Phenolic Component Profile and Analysis of Oleuropein Aglycon in Olive Oil by Atmospheric Pressure Chemical Ionization-Mass Spectrometry (APCI-MS)" is of further

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interest for methods of concentrating specific antioxidants from olive oils including oleuropein aglycon.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Drodge at telephone number 571-272-1140. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda Walker, can be reached at 571-272-1151. The fax phone number for the examining group where this application is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either private PAIR or Public PAIR, and through Private PAIR only for unpublished applications. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JWD

January 31, 2006


JOSEPH DRODGE
PRIMARY EXAMINER